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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,358	03/19/2004	Robert Harris	DIA1809-003D	3977
45684	7590	02/03/2006	EXAMINER	
ROGER A. GILCREST 250 WEST STREET COLUMBUS, OH 43216-7513			KIM, YUNSOO	
			ART UNIT	PAPER NUMBER
			1644	
DATE MAILED: 02/03/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/806,358	Applicant(s) HARRIS ET AL.	
	Examiner Yunsoo Kim	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 3-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/10/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-26 are pending.

2. Applicant's election without traverse of Group I, drawn to claims 1-2, a method to stimulate immune system, in the reply filed on 11/28/05 is acknowledged.

Claims 3-26 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 1-2 are under consideration in the instant application.

3. Applicants' claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. The priority date of the instant application is deemed to be 6/13/03.

4. Applicants' IDS filed on 1/10/06 has been acknowledged. However, the references 12 and 4 must be listed under the U.S. Patents and Foreign Documents, respectively. The reference 7 is deemed to be ISR for PCT/IB2004/002125 10/26/05 instead of PCT/IB2005 002135 8/11/05 is considered but has been crossed out as it is not appropriate for an information disclosure.

In addition, the reference 9 has not been considered as being non-English literature.

5. The specification is objected to because of the following informalities:
The Description of Figure is required for Figures (a-e) in the specification.

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-2 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-2 of copending Application No. 10/677,767. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

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8. The following is a quotation of the second paragraph of 35 U.S.C.112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

(A) The phrase “*in vitro*” recited in claim 1 is ambiguous and unclear as the method teaches administering antigen.

(B) The phrase “the current preprogrammed response” does not define metes and bounds of the invention.

(C) The term “modulate” or “immunomodulation” recited in claim 2 is ambiguous and unclear as the direction of modulating may be either “stimulatory” or “ suppressive”.

(D) The phrases “undesired current status” and “unwanted immune response” recited in claim 2 do not define metes and bounds of the invention.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.Pat. No. 6,093,396.

The ‘396 patent teaches a method for administering hGAD65 in immunological neutral formation (i.e. non-specific serum albumin in saline) for treating autoimmune diseases, IDDM (i.e. undesired/ unwanted status, col. 3, lines 23-47). The ‘396 patent further teaches modified hGAD65 is useful as an immunomodulant therapeutic to prevent certain autoimmune diseases (col. 4, lines 33-44).

In light of the specification [0002], GAD is defined as a major antigen and [0031] defines human serum albumin as an immunoneutral protein. Furthermore, the specification does not define “preprogrammed response”, “undesired current status” or “unwanted immune response”, those claimed limitations are interpreted as diseased condition as GAD associated with autoimmune diseases.

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As the reference teaches the administering the identical antigenic formulation in immunoneutral formulation, stimulating the immune system in vitro without interfering with the current preprogrammed response of immune system is an inherent property of the prior art teaching. Thus, the reference teachings anticipate the claimed invention.


12. No claims are allowable.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
January 23, 2006


Patrick J. Nolan, Ph.D.
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